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| 10/576,351 | 02/21/2007 | Georg Gradl | F-9052 | 7191 |
| 28107 7590 05/10/2010 JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168 | | | | |
| EXAMINER | | | | |
| BOLES, SAMEH RAAFIAT | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3775 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 05/10/2010 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,351

Applicant(s)

GRADL, GEORG

Examiner

SAMEH BOLES

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2010.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 32-69 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 32-69 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 4/17/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GS-08)
Paper No(s)/Mail Date 4/17/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2010 has been entered. Accordingly, Claims 1, 32, 38, 42 and 53 have been amended, claims 2-31 have been cancelled and claims 1, 32-69 are pending and have been examined in this office action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 32-34, 38-40, 46- 60, 66, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Frei et al. (US. Pub. No. 2003/0078581 A1).

Gotfried discloses a system for minimally invasive treatment of a fracture of a bone such as femoral fracture (see modified Figure 10 below), comprising an osteosynthetic plate (I) including a support section positionable with a support surface against said bone adjacent to the fracture and a fastening section for fixing said osteosynthetic plate to said bone; a fixation element (see modified Figure 10 below) for

fixing in a fragment of said bone that was dislodged by the fracture and comprising a shaft portion (10, Fig. 3), wherein said fixation element includes a screw head with a self-cutting thread (11); and a guide element (Fig. 6) including a first connecting section (15, Fig. 6) via which said guide element is fastenable to said osteosynthetic plate (see modified Figure 10 below) and a second connecting section for guiding said fixation element (see modified Figure 10 below), wherein said second connecting section of said guide element providing an inner bore (may be considered as a seat) (see modified Figure 7a below) in which a shaft of said fixation element is slidably and tightly received (col. 4, lines 59-60), such that the shaft portion of said fixation element is free from tilting therein and moveable axially with respect thereto; said guide element axially includes a rotational tool bore (16, Fig. 16) for receiving a rotational tool; said support section of said osteosynthetic plate has having at least first and second recesses (5, Fig. 2), said fixation element and said guide element being insertable into said bone through said first recess (see modified Figure 10 below), wherein said first recess in said support section and said guide element are configured such that a longitudinal axis of said guide element and a tangent on a side of said osteosynthetic plate facing said bone are at an angle; a fastening structure for holding said guide element axially fast in both directions after placement into said osteosynthetic plate, wherein said fastening structure includes a male thread (15, Fig. 6) provided on said first connecting section of said guide element and a female thread that provided in said first recess engageable with the male thread (abstract); said shaft and said second connecting section are configured in a circular shape such that an axial rotation of said fixation element is permitted in said

guide element, wherein said shaft of said fixation element includes catch surfaces that hold said fixation element rotationally fast in said seat; a rotation inhibiting structure for preventing rotation of the bone fragment dislodged by the fracture, wherein: said support section of said osteosynthetic plate includes at least a second recess; and said rotation inhibiting structure for preventing rotation includes a second fixation element (may be considered as an anti-rotation screw) (II, Fig. 10) that has a head and that can be placed into the dislodged fragment of said bone through said at least a second recess in said support section, wherein said at least a second recess has a female thread and said anti-rotation screw has a corresponding male thread (15, Fig. 6) at the head; and a target device (see modified Figure 10 below) that is detachable with said osteosynthetic plate via at least one clamping section, wherein said target device includes target bores that are aligned with the recesses in the osteosynthetic plate when said target device is connected to said osteosynthetic plate.

Gotfried failed to teach a non-rigid connection between the guiding element and said fixation element allowing back and forth movement of said fixation element along said longitudinal axis during healing of the fracture.

Frei teaches guide element (29, Fig. 3) and a fixation element (27), wherein the second connecting section of the guide element and the shaft portion of the fixation element being relatively positioned, wherein said positioning providing substantial alignment of said shaft portion along a longitudinal axis of said second connecting section for back and forth movement of said fixation element along said longitudinal axis

during healing of the fracture, and said movement and positioning providing a non-rigid connection between the guiding element and said fixation element (paragraph [20]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guide element and the fixation element of Gotfried to have a non-rigid connection relative to each other in view of Frei for providing an effective fixation system by adjustably allowing back and forth movement of said fixation element along said longitudinal axis during healing of the fracture.

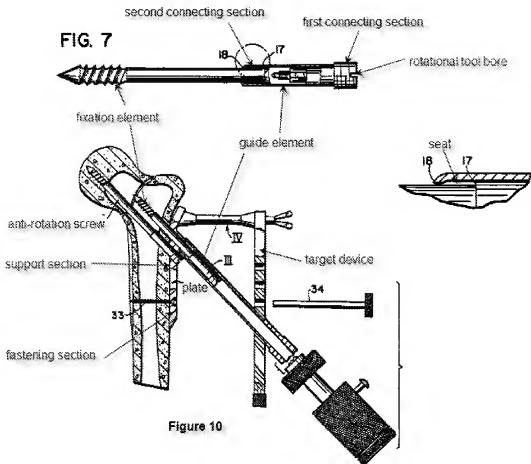
Gotfried in view of Frei failed to teach that the second connecting section provides a seat in comprising external seating surfaces and said shaft portion of said fixation element is contacts said external seating surfaces.

However, Applicant in the current application, teach different embodiments of the second connecting section (paragraph [36]), for example, Fig. 8 shows a second connecting section provides a seat comprising internal seating surfaces and said shaft portion of said fixation element is contacts said internal seating surfaces, and fig. 9 shows a second connecting section provides a seat comprising external seating surfaces and said shaft portion of said fixation element is contacts said external seating surfaces. And that is proving that both of embodiments (Figs. 8 and 9) are obvious variants. Therefore, it would have been an obvious to one skilled in the art at the time the invention was made to construct the second connecting section provides a seat comprising external seating surfaces in view of Fig. 9 of current application for providing

a non-rigid connection between the guide and the fixation elements, and for allowing back and forth movement between the guide and the fixation elements.

Also, Gotfried failed to disclose that the first recess in said support section and said guide element are configured such that a longitudinal axis of said guide element and a tangent on a side of said osteosynthetic plate facing said bone are at an angle of between 50° and 70° or at an angle of between 55° and 65°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the angle between the guide element and the osteosynthetic plate is between 50° and 70° or at an angle of between 55° and 65°, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

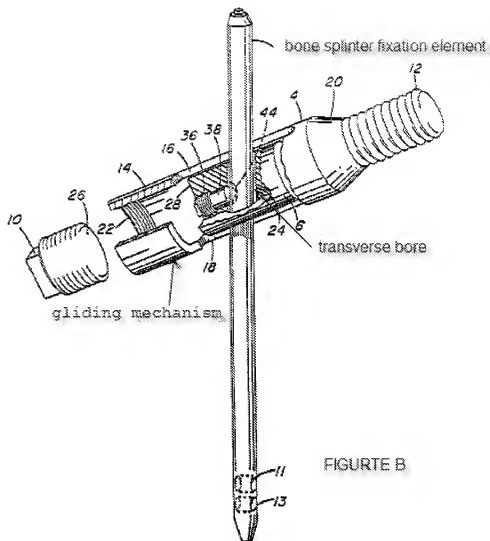


3. Claims 35, 41-44, 61-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Frei et al. (US. Pub. No. 2003/0078581 A1) and further in view of Nelson (US. Pat. No. 6,562,042 B2).

Gotfried in view of Frei discloses the claimed invention except an alignment structure operable to adjust and/or control a rotational position of said guide element relative to said osteosynthetic plate comprising: a bone splinter fixation element fixable in or to said guide element, wherein: said guide element includes a transverse bore; and said bone splinter fixation element fixable in said transverse bore.

Nelson discloses a system for treating a bone fracture comprising an alignment structure (see Figure B below) operable to adjust and/or control a rotational position of a gliding mechanism (may be considered as a guide element) comprising: a bone splinter fixation element fixable in said guide element, wherein: said gliding mechanism includes a transverse bore; and said bone splinter fixation element fixable in said transverse bore.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the system for treatment of a fracture of a bone of Gotfried in view of Frei with an alignment structure in view of Nelson for effectively controlling the rotational position of said guide element inside bone.



Gotfried in view of in view of Frei and Nelson disclose the claimed invention except that said longitudinal bone splinter fixation element and a longitudinal axis of said guide element create an angle of between 60 and 100° or an angle of between 70° and 90°.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the angle between the guide element and the bone

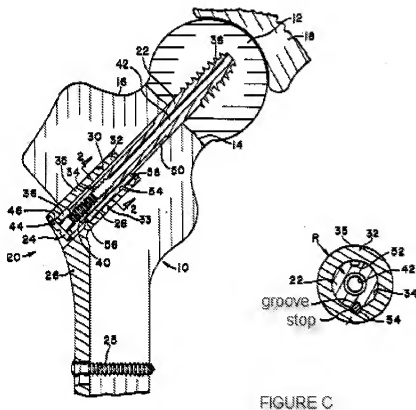
splinter fixation element is between 60 and 100° or an angle of between 70° and 90°, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

4. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Frei et al. (US. Pub. No. 2003/0078581 A1) and further in view of Lower (US. Pat. No. 4,612,920).

Gotfried in view of Frei discloses the claimed invention except that said fastening structure includes a groove provided in said first recess of said support section and a stop which is disposed in said groove for limiting a rotational movement of said guide element.

Lower discloses a system for treating a bone fracture comprising a fastening structure (see Figure C below) for holding a guide element axially fast in both directions after placement into a osteosynthetic plate, wherein said fastening structure includes a groove provided in said first recess of said support section and a stop which is disposed in said groove for limiting a rotational movement of said guide element.

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the fastening structure of Gotfried in view of Frei with a groove and a stop in view of Lower for effectively limiting the rotational movement of said guide element.

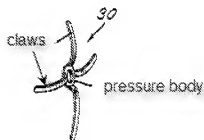
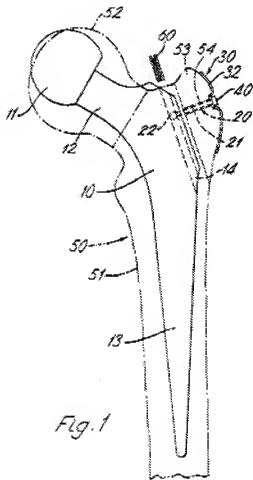


5. Claims 45 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotfried (US. Pat. No. 5,429,641) in view of Frei et al. (US. Pub. No. 2003/0078581 A1) and Nelson (US. Pat. No. 6,562,042 B2) and further in view of Lee et al. (US. Pat. No. 3,939,498).

Gotfried in view of Frei and Nelson disclose the claimed invention except that said bone splinter fixation element includes a screw that has a pressure body with claws.

Lee et al disclose a fixation system comprising of a bone fixation element includes a screw that has a pressure body with claws (see Figure D below).

It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to modify the bone splinter fixation element of Gotfried in view of Frei and Nelson with a pressure body with claws further in view of Lee et al for effectively securing the screw head of the bone splinter fixation element to bone.



Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMEH BOLES whose telephone number is (571)270-5537. The examiner can normally be reached on Monday - Friday 7:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAMEH BOLES/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775